

Application No. 10/797,481

REMARKS

Claims 21-24 and 28-36 are pending. By this Amendment, claim 21 is amended to more particularly and clearly point out Applicant's claimed invention. The specification supports the amendment of claim 21, for example, at page 1, lines 19-20, page 16, lines 6-7, Fig. 3 and throughout. Based on Applicant's clearly asserted scope for the previous language, Applicant does not intend to narrow the claim by this amendment. Also, Applicant has corrected a couple of typographical errors in the specification. No new matter is introduced by the amendments.

All of the pending claims stand rejected. Applicant respectfully request reconsideration of the rejection based on the following comments.

Rejection Under 35 U.S.C. § 102(b)

The Examiner rejected claims 21-23, 28, 29, 32, 33, 35 and 36 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,334,205 to Cain (Cain). In response to Applicant's previous arguments, the Examiner indicated that "Applicant is not claiming that the immobilization/fusion element (screw) is placed into the sacroiliac joint or the immobilization/fusion element is driven in the space between the ilium and the sacrum." Since Applicant was attempting to claim such a configuration, there was evidently some disagreement over the claim language. While Applicant maintains that the previous wording indicated this configuration, Applicant has amended the claim for clarity. In particular, Fig. 3 clearly shows this configuration for the fusion element.

In view of the clarifying amendment to claim 21, it is clear that the claim is directed to insertion of the immobilization element into the SI joint between the bones of the joint. Similarly, it is clear that Cain does not teach such a configuration since Cain only teaches placement of screws across the SI joint through the bones of the joint. Applicant incorporates by reference their arguments in the Amendment of July 26, 2006. In view of the clarifying amendment and comments, Cain clearly does not render the clarified claims *prima facie* anticipated. Applicant respectfully requests withdrawal of the rejection of claims 21-23, 28, 29,

Application No. 10/797,481

32, 33, 35 and 36 under 35 U.S.C. § 102(b) as being anticipated by Cain. While Applicant does not acquiesce with respect to any of the specific issues surrounding the dependent claims, these issues are presently moot in view of the issues presented above.

Rejection Over Cain and Cheng et al.

The Examiner rejected claim 24 under 35 U.S.C. § 103(a) as being unpatentable over Cain in view of U.S. Patent Publication 2002/0099288 to Chang et al. (Chang). The Examiner cited Chang for "real time imaging to guide the placement and orientation of an object." The deficiencies of the Cain reference with respect to teaching the basic features of the claimed invention are discussed above. Chang does not make up for the deficiencies of the Cain. In particular Chang does not teach immobilization of the SI joint using any procedure. Therefore, the combined teachings of Cain and Chang do not render claim 24 *prima facie* obvious.

With respect to the real time imaging features of claim 24, Applicant notes that Chang is directed to using ultrasound to place a portion of a hip replacement prosthesis as part of an invasive surgical procedure. There is no teaching in Chang that their procedure would be suitable for the placement of a pin into any joint during a less invasive procedure. Therefore, the combined teachings of Cain and Chang additionally do not lead to *prima facie* obviousness of the added feature in claim 24.

Due to these significant deficiencies in the combined teachings of Cain and Chang, Applicant respectfully requests withdrawal of the rejection of claim 24 under 35 U.S.C. § 103(a) as being unpatentable over Cain in view of Chang.

Rejection Over Cain and Bowman et al.

The Examiner rejected claims 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Cain in view of U.S. Patent 4,950,270 to Bowman et al. (Bowman). The Examiner cited Bowman for its teaching related to associating a screw with a biological agent. The deficiencies of Cain with respect to independent claim 21 are described above. Bowman does not teach

Application No. 10/797,481

procedures applied to the SI joint. Therefore, Bowman does not make up for the deficiencies of Cain with respect to Applicant's claimed invention. Since the combined teachings of Cain and Bowman do not render Applicant's claimed invention *prima facie* obvious, Applicant respectfully requests withdrawal of the rejection of claims 30 and 31 under 35 U.S.C. § 103(a) as being unpatentable over Cain in view of Bowman. While Applicant does not acquiesce in the assertions relating to the particular issues relating to biological agents in the context of these claims, Applicant does not comment further here due to the clear deficiencies already described above.

Rejection Under 35 U.S.C. § 103(a) Over Cain

The Examiner rejected claim 34 under 35 U.S.C. § 103(a) as being unpatentable over Cain. In particular, the Examiner has asserted that it "would have been a matter of design choice to one skilled in the art at the time the invention was made to construct the immobilization/fusion element without any threads, since applicant has not disclosed that such solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purposes of providing an immobilization/fusion element of the joint." With all due respect, Applicant disagrees with this. However, Applicant is grateful for the Examiner's well articulate assertion in this regard since an explanation of why this statement is not true will help clarify the inventive nature of the overall procedure. Also, Applicant has noted the general deficiency of Cain above with respect to claim 21. Applicant respectfully requests reconsideration of the rejection based on the following comments.

Applicant has been a pioneer that has successfully used an open surgical procedure for SI fusion to treat several hundred patients. This procedure is not directed to the treatment of SI fractures, breaks or the like. This procedure is directed to joint pain from the SI joint. While the SI joint does not move a large amount during movement, friction in the joint can lead to severe

Application No. 10/797,481

pain. Clearly, the SI joint is not amenable with present technology to joint replacement due to the extreme complexities relating to nerve and blood vessel placement passing through the joint from the torso to the legs.

The SI joint is held in place with a large number of strong ligaments. The SI joint is essentially unique in that distention of the joint is suitable for immobilization. In other words, an implant that applies forces that push the joint apart due to the placement of an implant into the joint is suitable to fuse the joint. In contrast, Cain teaches pulling the joint together. This is the opposite effect of distending the joint. Thus, Cain teaches away from using an unthreaded implant placed into the joint to distend the joint. An unthreaded implant would not be expected to hold in place within the Cain procedure. The strong ligaments hold the joint together while the immobilization element in Applicant's claimed procedure distends the joint to immobilize the joint. Since Cain teaches away, from using an unthreaded implant, which would not be suitable to compress the joint, Cain clearly does not render Applicant's claimed invention *prima facie* obvious.

Since Cain does not render claim 34 *prima facie* obvious, Applicant respectfully requests withdrawal of the rejection of claim 34 under 35 U.S.C. § 103(a) as being unpatentable over Cain.

CONCLUSIONS

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested.

The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Application No. 10/797,481

Respectfully submitted,

A handwritten signature in black ink, reading "Peter S. Dardi". The signature is fluid and cursive, with the first name "Peter" and last name "Dardi" clearly legible.

Peter S. Dardi, Ph.D.
Registration No. 39,650

Customer No. 62274
Dardi & Associates, PLLC
U.S. Bank Plaza, Suite 2000
220 South 6th Street
Minneapolis, Minnesota 55402
Telephone: (404) 949-5730